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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,474	12/08/2003	Thomas Sandal	5600.210-US	2856

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,474	SANDAL ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/426,340.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1203*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species of amylase and the species of a hydrolase in the reply filed on March 27, 2007 is acknowledged. The traversal is on the ground(s) that "it would not be an undue burden for the Examiner to search all of the species." Upon further consideration, as the examiner found that a search of the entire invention as claimed was not unduly burdensome, the examiner concurs with applicant. Accordingly, the Election/Restriction Requirement of September 25, 2006 is **withdrawn**.

Priority

2. It is noted that as the instant application is a continuation of US application no. 09/426,340, the first line of the specification should be updated so as to provide the current status of the '340 application (i.e., to state that the '340 application is "now US Patent 6,723,504").

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-20 are indefinite over the recitation of the terminology "an environmental pool of microorganisms." The specification defines the term "an environmental pool of organisms" as meaning "an environmental sample comprising

microorganisms and cells from higher animals harboring DNA encoding a polypeptide with an activity of interest" (see definition at page 3 of the specification). However, while the specification does employ the terminology "environmental pool of microorganisms" with regard to a few particular types of samples (see, e.g., page 5 of the specification), the specification does not provide a definition for this term, or make clear how or whether "an environmental pool of microorganisms" differs from the defined "environmental pool of organisms." For example, does this terminology encompass samples that include organisms or cells that are not microorganisms, or does the use of the term "microorganisms" limit the claims to samples that only include microorganisms? If the latter is the case, are the claims therefore limited to samples that are known to only contain microorganisms (e.g., to samples that have been screened so as to rule out the presence of other cells or organisms types)? As neither the specification nor the prior art clearly set forth the scope and meaning of the term "an environmental pool of microorganisms," the types of "environmental pools" that would actually be encompassed by the instant claims is not clear.

Claim 20 is indefinite over the recitation of the limitation "the polypeptide with an activity of interest" because there is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-6, 8-9, 12-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Okuta et al (Gene 212:221-228 [6/1998]).

It is noted that provisional application 60/106,319 does not disclose the claimed invention; for example, the provisional application never refers to an "environmental pool of microorganisms," as set forth in the instant claims, and therefore does not provide basis for the types of environmental samples now encompassed by the claims. Accordingly, the instant application has an effective filing date of October 25, 1999 (i.e., the filing date of parent application 09/426,340), and the Okuta et al reference qualifies as prior art under 35 USC 102(b).

Okuta et al disclose methods in which catechol 2,3-dioxygenase (C23O) gene libraries are prepared and in which DNA sequences in said libraries are identified (see entire reference, particular pages 222-224). The method of Okuta et al comprises a step of cultivating bacteria-containing samples of soil or sea water on media containing substrates for C23O genes (specifically, phenol or crude oil); followed by PCR amplification and cloning of DNA templates prepared directly from bacterial cells growing "on phenol or crude oil as the carbon source" (see pages 222-224, particularly the right column of page 223). As it is a property of the bacteria-containing soil and sea water samples that they constitute types of environmental pools of microorganisms, the samples employed by Okuta et al are encompassed by the instant claims. Thus, Okuta et al set forth a method meeting the requirements of independent claim 1. Regarding independent claim 14, it is further noted that Okuta et al also disclose screening the

libraries prepared by their methods for DNA sequences encoding their polypeptide of interest (i.e., encoding polypeptides having C230 sequences as determined by nucleic acid sequencing; see pages 222, right column and 224, right column).

Regarding dependent claims 2-3, 15, and 20, it is again noted that the media employed by Okuta et al is disclosed by Okuta et al as being enriched with C23O substrates (specifically, phenol and crude oil), and that Okuta et al state that phenol or crude oil constitute the carbon source in their media (see above). Regarding claims 5-6, the phenol or crude oil containing media of Okuta et al is growth restricted in that only phenol-degrading bacteria grow on the media; further, the media pH and incubation temperature employed by Okuta et al inherently affect whatever growth occurs on said media, such that the cultivation conditions employed by Okuta et al include growth restrictions that "comprise pH and temperature," as required by claim 6. Regarding claims 8 and 16, Okuta et al disclose the screening of their libraries for active C23O enzymes, and disclose that their method results in enrichment for DNA sequences encoding C23O enzymes (see entire reference, particularly page 224). With respect to claims 9 and 17, it is an inherent property of the C23O enzymes taught by Okuta et al that they are oxidoreductases. Regarding claims 12-13, Okuta et al disclose that their soil and sea water samples comprise bacteria producing C23O enzymes (see, e.g., page 223, right column).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4, 7, 10-11, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okuta et al (Gene 212:221-228 [6/1998]) in view of Sarkar et al (Folia Microbiologica 38(1):29-32 [1993]).

Okuta et al disclose methods in which catechol 2,3-dioxygenase (C23O) gene libraries are prepared and in which DNA sequences in said libraries are identified (see entire reference, particular pages 222-224). The method of Okuta et al comprises a step of cultivating bacteria-containing samples of soil or sea water on media containing substrates for C23O genes (specifically, phenol or crude oil), followed by PCR amplification and cloning of DNA templates prepared directly from bacterial cells growing "on phenol or crude oil as the carbon source" (see pages 222-224, particularly the right column of page 223). Okuta et al also disclose screening the libraries prepared by their methods for DNA sequences encoding their polypeptide of interest

(i.e., encoding polypeptides having C230 sequences as determined by nucleic acid sequencing; see pages 222, right column and 224, right column). The phenol or crude oil containing media of Okuta et al is growth restricted in that only phenol-degrading bacteria grow on the media. Further, Okuta et al disclose the screening of their libraries for active C23O enzymes, and disclose that their method results in enrichment for DNA sequences encoding C23O enzymes (see entire reference, particularly page 224).

Okuta et al state that their method allows one to "isolate functional C23O genes without isolating bacteria," that the method is "useful for establishing a library of functional hybrid genes reflecting the diversity in the natural gene pool," and that their method is "generally applicable, and may be useful in establishing a divergent hybrid gene library for any gene family" (p. 225). Okuta et al further note that the "isolation and screening of novel enzymes are both important objectives in biotechnology," and that their method "may be useful for the exploitation of new genes useful for industry, medicine, and basic sciences" (p. 226). However, Okuta et al do not disclose the use of media containing a substrate meeting the requirements of claim 4, or disclose an "enzyme of interest" meeting the requirements of claims 10-11 and 18-19. Okuta et al also fail to disclose the particular growth restrictions of claim 11.

Sarkar et al teach that cellulases are produced "by many cellulolytic microorganisms," and disclose that *Bacillus thermoalcaliphilus* isolated from "the soil of a termite" produces a cellulase that is most stable at pH 8.5-9.5 and optimally active at 70°C (see entire reference, especially p. 29-30). Sarkar et al teach growth of this bacterium in media comprising cellulose at 60°C, pH 8.5 (p. 29). Sarkar et al further

note that "the high temperature and high pH optima found here [with respect to the novel cellulose] give good promise for the practical application of the present enzyme and/or microorganism" (p. 32).

In view of the teachings of Sarkar et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Okuta et al so as to have prepared from a termite soil sample a library enriched for cellulase genes encoding thermostable cellulases such as that taught by Sarkar et al, and to have screening or selected such genes for further analysis. An ordinary artisan would have been motivated to have made such a modification for the advantage of, e.g., rapidly isolating and sequencing thermostable cellulase-encoding genes, and/or rapidly preparing recombinant forms of such cellulases for additional study or use. The usefulness of such cellulases is noted by Sarkar et al, and given the teachings of Okuta et al with regard to the general applicability of their method to other gene types, an ordinary artisan would have had a reasonable expectation that such methods could be carried out successfully. It is also noted that as it is a property of termite soil samples that such samples comprise microorganisms and are obtained from the environment, such samples meet the requirements of the instant claims.

With respect to claim 4, it is again noted that Sarkar et al disclose that cellulose is a substrate for cellulase, and teach growth of cellulase producing organisms in media comprising cellulose. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have selected cellulose as the substrate in practicing the method of Okuta et al in view of Sarkar et al for the

advantage of enriching for the growth of the desired cellulase-producing bacteria. Regarding claim 7, it would also have been *prima facie* obvious to one of ordinary skill in the art to have selected the growth conditions taught by Sarkar et al for use in the method of Okuta et al in view of Sarkar et al in order to have assured optimal growth of thermostable-cellulase producing bacteria; the growth conditions taught by Sarkar et al meet the requirements of the claim. Regarding claims 11 and 19, it is noted that thermostable cellulases are among the enzymes encompassed by the claims. Finally, regarding claims 10 and 18, as Sarkar et al teach the usefulness of thermostable cellulases, and as Okuta et al teach that their method is generally applicable to any type of gene (see above), it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have also enriched and screened samples of the type taught by Sarkar et al for the presence of cellulase-related enzymes such as hemicellulases, using the method suggested by Okuta et al in view of Sarkar et al, and employing the well-known, relevant substrate for hemicellulase (specifically, hemicellulose), for the advantage of, e.g., rapidly isolating and identifying useful thermostable hemicellulases.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,723,504. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims and the '504 claims are each drawn to methods for generating gene libraries (see instant claim 1 and claims dependent therefrom, and claim 1 of the '504 patent and claims dependent therefrom) and to methods of identifying a DNA sequence encoding a polypeptide of interest (see instant claim 14 and claims dependent therefrom, and claim 20 of the '504 patent and claims dependent therefrom). Both the instant claims and the '504 claims include steps of subjecting an environmental pool to cultivation under particular conditions, and preparing a gene library from the enriched environmental pool, with the DNA identification method claims further including a step of library screening. The instant claims differ from the '504 claims in reciting an "environmental pool of microorganisms" rather than an "environmental pool of organisms isolated from soil, animal dung, insect dung, insect gut, animal stomach, sea or lake water, waste water, sludge, or sediment." However, the '504 specification

defines the language "environmental pool of organisms" as including environmental samples comprising microorganisms, and the sample types listed in the '504 claims are each types of samples that are known to include microorganisms. Further, the instant claims clearly encompass environmental samples that include microorganisms. As noted above, the instant specification does not provide any kind of definition for the term "environmental pool of microorganisms" or otherwise set forth any limitations on this terminology that would, e.g., exclude the types of samples set forth in the '504 claims. Accordingly, as the sample types set forth in the '504 claims are in fact environmental pools comprising microorganisms, the '504 claims anticipate the instant claims, such that the instant claims and the '504 claims are not patentably distinct.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Diana B. Johannsen
Primary Examiner
Art Unit 1634